

EPAUnited States Environmental Protection Agency
Washington, DC 20480**Work Assignment**

Work Assignment Number

0-03

☐ Other ☐ Amendment Number

Contract Number

EP-W-11-020

Contract Period 02/01/2011 To 01/31/2012

Base ☒ Option Period Number

Title of Work Assignment/SF Site Name

Verification of EFED Database

Contractor

CAMBRIDGE ENVIRONMENTAL, INC.

Specify Section and paragraph of Contract SOW

Task F

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 02/01/2011 To 01/31/2012

Comments:

In accordance with contract clause B.2 "Work Assignments", please submit two (2) copies of a work plan to the Project Officer (PO) and one (1) copy to the Contracting Officer (CO) within fourteen (14) calendar days after receipt of this work assignment initiation. The work plan shall include a detailed technical and staffing plan with incorporated QA elements and a detailed cost estimate.

☐ Superfund

Accounting and Appropriations Data

☒ Non-SuperfundSFO
(Max 2)

Note: To report additional accounting and appropriations data use EPA Form 1900-68A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:

Cost/Fee:

LOE: 0

02/01/2011 To 01/31/2012

This Action:

340

Total:

340

Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee:

LOE:

Cumulative Approved:

Cost/Fee:

LOE:

Work Assignment Manager Name Cara Dzubow

Branch/Mail Code:

Phone Number 703-305-5659

FAX Number:

(Signature)

(Date)

Project Officer Name Cara Dzubow

Branch/Mail Code:

Phone Number 703-305-5659

FAX Number:

(Signature)

(Date)

Other Agency Official Name

Branch/Mail Code:

Phone Number:

FAX Number:

(Signature)

(Date)

Contracting Official Name Jody Gosnell

Branch/Mail Code:

Phone Number 202-564-4353

FAX Number:

(Signature)

(Date)

**Statement of Work for New Work Assignment under the contract Titled:
“Technical Support for the Assessment of Ecological Effects, Fate and
Transport Pesticides in the Environment”**

Work Assignment Title:

Verification of the OPP Environmental Fate and Effects Division Ecotoxicity Database

I. Contract-Level Information:

1. **Contract Title:** Technical Support for Assessment of the Ecological Effects, Fate and Transport of Pesticides in the Environment
2. **Contract No.** EP-W-11-020
3. **Name of Contractor:** Cambridge Environmental Inc
4. **Option Period #:** Base Period (2/01/11 – 1/31/2012)
5. **Contracting Officer:** Jody Gosnell (202-564-4353) gosnell.jody@epa.gov
6. **Project Officer:** Cara Dzubow 703-305-5659 dzubow.cara@epa.gov
Alternate PO: Brian Montague 703-305-6438 montague.brian@epa.gov
7. **Quality Manager:** Mark J Huff 703-308-0476 huff.markj@epa.gov
8. **EFED Courier Address:** One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22203

II. Work Assignment-Level Information:

- Work Assignment # & Title:** WA #0-03: Verification of the OPP Environmental Fate and Effects Division Ecotoxicity Database
9. **Action Code:** None
 10. **Fees for Service:** N
 11. **WAM:** Brian Montague 703-305-6438 montague.brian@epa.gov
 12. **Technical Experts:** Mark J Huff 703-308-0476 huff.markj@epa.gov

III. Work Assignment-Level Information:

13. **Contract Task #/Name:** Task F

IV. Technical Direction-Level Information:

14. **Technical Direction Title:** Development of a Problem Formulation for the Reregistration of Sumithrin

Background:

Since 1991, the Office of Pesticide Programs' (OPP) Environmental Fate and Effects Division (EFED) has maintained a database of ecotoxicity data. The database incorporates summaries of ecological toxicity and consists of over 22,000 records representing 700 different active ingredients, inert ingredients, and metabolites. These data are derived from studies that have been reviewed and categorized as fully or partially acceptable for fulfillment of pesticide registration and reregistration guideline requirements as explained under FIFRA Subdivision E, Parts 158.145 and 158.150. The purpose of this database has been to provide a readily accessible up-to-date summary of EFED reviewed ecological effect [toxicity] data for pesticide active ingredients, based on technical grade products and in some cases formulated products, presently registered or previously manufactured in the U.S. for both terrestrial and aquatic animals and plants. The current database includes data from registrant-submitted studies, studies conducted by USEPA, U. S. Department of Agriculture and U. S. Fish and Wildlife Service laboratories over the last 25 years, and data from published studies which have been reviewed by OPP scientists and considered to meet OPP guideline criteria for acceptable data.

OPP, Office of Water (OW) and the Office of Research and Development (ORD) are currently engaged in an effort to harmonize the process used by the OW and OPP to conduct ecological effect characterizations relative to aquatic organisms. The harmonization effort is more thoroughly described in the scoping document (http://www.epa.gov/oppefed1/cwa_fifra_effects_methodology/scope.html) developed between OW and OPP. The scoping document discusses the potential role that OPP data can play in OW efforts to develop Aquatic Life Criteria (ALC) for pesticides. Part of that process would be the ability to readily share data with OW and to develop tools that would enhance abilities of the two offices to estimate potential data based on the toxicity of similarly structured compounds. As such, a number of approaches to generate synthetic data are under consideration; these include the use of analog data, read-across, and [quantitative] structure-activity relationships. To facilitate this process, it is critical to insure that EFED toxicity database is an accurate representation of the existing data.

Over the years that the database has evolved, it has relied on information recorded in data evaluation records (DERs) completed by EFED science staff for each of the studies reviewed. As various actions have come into the Division requiring that data are reviewed again, some discrepancies between the DERs and how the information is recorded within the database have been observed. Additionally, inconsistencies in how data are reported in DERs have also been identified which have in turn led to inconsistencies in how data are recorded in the EFED toxicity database. Through a series of internal discussion between the database management branch, i.e., Environmental Services Support Branch (EISB), EFED senior science staff and EFED management, it has also become apparent that expectations regarding what the data are intended to represent may differ among EFED scientists. Because of inconsistencies and differences in opinion on what the dataset actually represents, there is a critical need to better define the critical elements of the database and verify that the database is consistently populated with the appropriate data elements from each study, as well as any additional elements from each study which are felt to be needed.

Technical Direction:

The purpose of this project is to systematically verify that the data contained in the EFED toxicity database matches the finalized data evaluation records (DERs) from which the data were extracted. Initially, only aquatic plant and animal data will be verified and this process will proceed according to mode of action for the target species starting with Acetylcholinesterase (AChE) inhibition MOA including the organophosphate and N-methyl carbamate insecticides- EFED and OW will provide contractor with a prioritized list of chemicals to verify/correct (Attachment #1). Data for additional MOAs will be reviewed in the order identified by EFED/OW staff. MOA will be entered into each line of data as a new field. For chemicals other than the AChE inhibitors, target organism MOA will be identified using the ASTER MOA tool.

Important note- none of the data from Mayer and Ellerseick or other federal laboratories will be reviewed/verified as part of this effort.

Task 1: Develop a Staffing Plan

The staffing plan is a formal document describing in comprehensive detail the necessary technical activities, staffing requirements, and QA/QC activities that must be implemented to ensure that the results of the work performed will satisfy the needs and criteria identified in this plan. After reviewing the information provided in the attachments, the contractor shall submit a staffing plan written in accordance with all applicable elements (i.e. A1-A9, B9, B10, C1-C2, and D1-D3) of the EPA/QA R-5 document, EPA Requirements for Quality Assurance Project Plans, in consultation with the EPA/QA G-5 guidance document (USEPA, 2001; 2002). Within the staffing plan, the contractor shall clearly identify any points of clarification or additional information needed, which were not already addressed in the SOW. This staffing plan shall also clearly indicate any proposed changes in staffing levels, costs and/or time frames from those proposed in this SOW, along with reasons for any proposed changes.

The contractor shall submit a staffing plan within 10 business days upon receipt of this SOW. The EFED TOPO and EFED Quality Manager must review the staffing plan, providing electronically submitted feedback to the contractor. A conference call may be scheduled to occur within 1-4 business days after EFED's electronic submission of its feedback, in order to discuss the contractor's revised staffing plan. The contractor shall incorporate any decisions resulting from the conference call into the staffing plan, which is then to be submitted to EFED within 1 business day after the conference call and/or other forms of feedback. Before beginning work on any other tasks within this technical direction, the contractor shall receive notification from the EFED PO that the EFED TOPO and EFED QAM have reviewed and approved the final staffing plan.

- ***Task 1 Deliverable/s- Draft and Final Staffing Plan***

Task 2: Verify Accuracy of Database against DERs and add/update new dose-response data

EISB staff will provide the electronic DERs for review to the contractor as well as an electronic copy of the current ecotoxicity database containing the chemicals/records to be QC'd (Attachment #2). The DERs used in the verification process will be the final signed DER and should contain the full complement of signatures. The DERs should be consistent with the MRID and scan barcode listed in the EFED database for that particular study data. Only core, supplemental and/or acceptable studies will be included in the analysis. Additionally, any data from Industrial BioTest Laboratories (IBT) which do not have an associated confirmation memo with the DER will be classified as invalid and updated in the EFED toxicity database as part of this effort.

The contractor will verify each of the 35 fields represented in the EFED database against the information contained in the DER; these fields are listed in Attachment #3.

If there is a discrepancy between the DER and the EFED toxicity database value, the contractor will adjust the value in the database to be consistent with the DER and denote that a record has been updated.

Special attention will be given toward insuring that the data are expressed as active ingredient [or active equivalent, where appropriate] and are reported using the similar units: mg ai/L [ppm] or ug ai/L [ppb]. Ideally, the values contained in the database should be normalized to one particular unit of measurement even if the DER does not report the value as such. Summary toxicity data will be verified by the contractor using the conclusions/executive summary section of the DERs; these pages are typically either the first or second page of the DER.

If not already captured in the EFED toxicity database, the study MRID or accession number and the DER scan barcode will be entered to insure transparency.

If the DER indicates that a record corresponds to a formulated product exposure, the contractor should note this. Records pertaining to formulated product exposures should not be QC'ed.

Below is summary of the tasks to be performed:

1. Verify/Correct all of the endpoints in the database to match the current DER information according to the prioritization list of chemicals.
 - a. Confirm/update that all of the endpoints in the database are to be reported in terms of active ingredient;
2. Verify/Correct records in the database to reflect EFEDs current study classification of the DER
 - a. DER/records in the database that are currently classified as either unacceptable or invalid should not be updated other then to confirm/update the study status = either unacceptable or invalid in the database.

▪ ***Task 2 Deliverable/s- Updated/Verified EFED toxicity database***

Quality Objectives and Criteria:

The Data Quality Objectives (DQO) are to insure that the EFED toxicity database is an accurate reflection of the DERs used to derive the data such that the database represents a compendium of the acute and chronic toxicity data from studies reviewed by EFED. These data represent both the technical grade active ingredient (TGAI) and formulated products plus degradates where available. The level of precision is determined by the available data as written in the DER. A value in the EFED toxicity database is considered correct, if it has been transcribed accurately. No attempt will be made to second guess the judgment of the scientists who completed the DER.

Thus, the data quality objectives are:

- 95% of the toxicity values cited in the EFED toxicity database are accurate reflections of what is contained in the DERs
- 95% of the toxicity values are reported as active ingredient (ai) or active equivalents (aeq)
- 100% of target species MOA is identified as a new field

List of Attachments:

Attachment 1 – List of Aquatic Chemicals for Verification

Attachment 2 – DERs for Chemicals to be verified

Attachment 3 – MS Access version of EFED Ecotoxicity Database to be used for verification

Attachment 4 - Data Entry Fields for Ecotoxicity Database

Attachment 5 - Quality Assurance Project Plan- Verification Of The Opp Environmental Fate And Effects Division Ecotoxicity Database

EPAUnited States Environmental Protection Agency
Washington, DC 20460**Work Assignment**

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Contractor

CAMBRIDGE ENVIRONMENTAL, INC.

Specify Section and paragraph of Contract SOW

Purpose:

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Work Assignment

☐

Work Assignment Close-Out

☐

Work Assignment Amendment

☐

Incremental Funding

☒

Work Plan Approval

Period of Performance

From 02/01/2011 To 01/31/2012

Comments: The purpose of this amendment is to approve of the contractor Work Plan dated 5/16/2011.

☐

Supertund

Accounting and Appropriations Data

☒

Non-Supertund

SFO
(Max 2)☐

Note: To report additional accounting and appropriations data use EPA Form 1900-68A.

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1										
2										
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4										
5										

Authorized Work Assignment Ceiling

Contract Period: 02/01/2011 To 01/31/2012 Cost/Fee: \$0.00 LOE: 0

This Action: \$23,703.27 400

Total: \$23,703.27 400

Work Plan / Cost Estimate Approvals

Contractor WP Dated: 05/16/2011 Cost/Fee: \$23,703.27 LOE: 400

Cumulative Approved: Cost/Fee: \$23,703.27 LOE: 400

Work Assignment Manager Name Cara Dzubow

Branch/Mail Code:

Phone Number 703-305-5659

FAX Number:

(Signature)

(Date)

Project Officer Name Cara Dzubow

Branch/Mail Code:

Phone Number: 703-305-5659

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(Signature)

(Date)

Other Agency Official Name Jennifer Garger

Branch/Mail Code:

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FAX Number:

(Signature)

(Date)

Contracting Official Name Jody Gosnell

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FAX Number:

(Signature)

(Date)